**510(k) SUMMARY**
**Spectrum Spine's SPINOUS PROCESS DEVICE**

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| **Date:** | October 15, 2013 | |
| **Contact:** | Dr. Jim Robinson<br>404-550-1335 | Spectrum Spine IP Holdings, LLC<br>3045 Paces Lake Court<br>Atlanta, GA 30339 |

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| **Trade Name:** | Spectrum Spine SPINOUS PROCESS DEVICE |
| **Common Name:** | Interspinous Process Device |
| **Product Class:** | Class II |
| **Classification:** | 21 CFR §888.3050 |
| **Product Code:** | PEK |
| **Panel Code:** | 87 |

**Name/Address of Sponsor**

NOV 1 2 2013

Spectrum Spine IP Holdings, LLC
3045 Paces Lake Court
Atlanta, GA 30339
404-550-1335

***Purpose:***
The purpose of this submission is clearance of the Spectrum Spine SPINOUS PROCESS DEVICE as a new medical device that is substantially equivalent to the predicate devices.

**Device Description**
The Spectrum Spine Spinous Process Device is a permanent implant device with plates and rods made from Titanium Alloy per ASTM F136 and Commercially Pure Titanium per ASTM F67 and cages made from polyetheretherketone (Zeniva PEEK 500 per ASTM F2026-10, PEEK Polymer for surgical implant applications). It is a posterior, non-pedicle supplemental fixation device. The device provides plates, cages and connecting rods of various shapes and sizes to provide supplemental stabilization of the spinous process to support fusion.

**Predicate Device**
The predicate devices are the Lanx Aspen Spinous Process Fusion Plate (K071877) and the X-spine Axle device (K112592).

**Intended Use / Indications for Use**
The Spectrum SPINOUS PROCESS DEVICE is a posterior, non-pedicle supplemental fixation device, intended for use at a single-level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation and attachment to spinous processes for the

purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain or discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation), and/or tumor. The Spectrum Spine SPINOUS PROCESS DEVICE is intended for use with bone graft, and is not intended for standalone use.

**Performance Data**

Performance data for the Spectrum Spine SPINOUS PROCESS DEVICE included static and dynamic compression bend, static torsion, locking screw torque strength, axial push off strength from simulated bone and rod dissociation strength. Most testing was completed per ASTM 1717-12 and ASTM F1798-97.

**Summary:**

The Spectrum Spine SPINOUS PROCESS DEVICE is substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Means of fixation

There are no significant differences in technological characteristics compared to the predicate devices. Spectrum Spine considers this device to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

Spectrum Spine
% Silver Pine Consulting
Rich Jansen, Pharm.D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K130066
Trade/Device Name: Spectrum Spine Spinous Process Device
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: October 15, 2013
Received: October 17, 2013

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K130066

Device Name: Spectrum Spine SPINOUS PROCESS DEVICE

Indications for Use:

The Spectrum SPINOUS PROCESS DEVICE is a posterior, non-pedicle supplemental fixation device, intended for use at a single-level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation and attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain or discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation), and/or tumor. The Spectrum Spine SPINOUS PROCESS DEVICE is intended for use with bone graft, and is not intended for standalone use.

| Prescription Use ___V____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130066